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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,214

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Roger D.A. Lipman

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CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER

GHALI, ISIS A D

ART UNIT

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12/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/069,214	Applicant(s) LIPMAN, ROGER D.A.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9-13, 15 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9-13, 15, 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/14/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE and IDS both filed 10/14/2008.

Claims 1-5, 7, 9-13, 15, 21-23 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed 12/04/2006 introduced new matter that was not described in the specification as originally filed. The recitation of "uncomplexed hydrocolloid composition". Recourse to the specification, no disclosure of "uncomplexed hydrocolloid composition". the specification disclosed cyclodextrin as complexed and uncomplexed form, and not the hydrocolloid composition, see for examples pages 4 and 14. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,231,369 ('369) in view of US 5,429,628 ('628).

US '369 teaches an adhesive sealing material for use in connection to ostomy devices composed of continuous rubber phase and hydrocolloid dispersed in the continuous phase, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-60).

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Example O, Table III, shows that the styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition, which read on the instantly claimed amounts because claim 4 recites up to 50% polyisobutylene and claim 5 recites up to 15% of styrene polymer. The hydrocolloid is a mixture of more than one hydrocolloid in an amount ranges from 48-56 % (col.8, lines 52-54; Example O, Table III). The composition further comprises oils, medicaments, or bactericides (col.6, lines 33, 45-47). The composition is supplied by release liner, i.e. substrate (col.9, lines 1-2).

The reference does not teach uncomplexed cyclodextrin among the hydrocolloids as claimed by claim 1, the amount of cyclodextrin as claimed by claim 3, or the material of the substrate as claimed in claim 15.

The material of the substrate does not impart patentability to the claims, and one having ordinary skill in the art would have determined the substrate material according to the specific intended use.

US '628 teaches compositions and articles such as catamenials, diapers, pantliners, paper towels, tissues, underarm shields, etc., which minimize odor caused from body fluids through the incorporation of an odor controlling effective amount of uncomplexed cyclodextrin (abstract; col.2, lines 28-30). Example 1 shows the composition/article comprises up to 20% of uncomplexed cyclodextrin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an adhesive composition useful for medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as disclosed by US '369, and add up to 20% of

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uncomplexed cyclodextrin to the mixture of hydrocolloid phase as disclosed by US '628. One would have been motivated to do so because US '628 teaches that such an amount of uncomplexed cyclodextrin minimizes odor caused from body fluid. One would reasonably expect formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising uncomplexed cyclodextrin that effectively provides minimal odor from the body fluids.

6. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,367,732 ('732) in view of US '628.

US '732 teaches a skin barrier comprises an adhesive layer comprising discontinuous hydrocolloid phase dispersed in a continuous phase comprising styrene copolymers and polyisobutylene (abstract; col.5, lines 24-26, 49; col.6, lines 35-36; col.8, lines 31-42, 62-64). The adhesive composition further comprises bacteriostatic or fungicidal agents (col.6, line 59). The hydrocolloid phase comprises at least one hydrocolloid, and forms 10-55% of the composition of the adhesive layer (col.8, lines 53-55; col.9, lines 22-23). The styrene copolymer forms 10-40% of the continuous phase (col.9, line 16). The skin barrier further comprises a non-adhesive, water impervious film secured to the adhesive layer (col.3, lines 54-56).

The reference does not teach uncomplexed cyclodextrin among the hydrocolloids as claimed by claim 1 or its amount as claimed by claim 3.

US '628 teaches compositions and articles such as catamenials, diapers, pantliners, paper towels, tissues, underarm shields, etc., which minimize odor caused from body fluids through the incorporation of an odor controlling effective amount of uncomplexed cyclodextrin (abstract; col.2, lines 28-30). Example 1 shows the composition/article comprises up to 20% of uncomplexed cyclodextrin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition for adhesive barrier comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as disclosed by US '732, and add up to 20% of uncomplexed cyclodextrin to the mixture of hydrocolloid phase as disclosed by US '628. One would have been motivated to do so because US '628 teaches that such an amount of uncomplexed cyclodextrin minimizes odor caused from body fluid. One would reasonably expected formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising uncomplexed cyclodextrin that effectively provides minimal odor from the body fluids.

7. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/14282 ('282) in view of US '628.

WO '282 teaches a pressure sensitive adhesive material comprising continuous phase of rubber comprising styrene copolymer and polyisobutylene; and a discontinuous phase comprising hydrocolloid (abstract). The discontinuous phase forms

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15-70 wt % of the composition (page 11, first paragraph). The styrene copolymer forms 10-30 wt % of the composition, and the polyisobutylene forms 20-60 wt % of the composition (page 15, claims 1-4). Examples 1 and 2, page 13, shows that the composition comprising more than one hydrocolloid including CMC and pectin. The composition comprises bactericides (page 11, third paragraph). The adhesive composition is coated on non-adhesive waterproof film and used in adhesive barrier or dressing for medical use (page 16, claim 13).

The reference does not teach uncomplexed cyclodextrin among the hydrocolloids as claimed by claim 1 or its amount as claimed by claim 3.

US '628 teaches compositions and articles such as catamenials, diapers, pantliners, paper towels, tissues, underarm shields, etc., which minimize odor caused from body fluids through the incorporation of an odor controlling effective amount of uncomplexed cyclodextrin (abstract; col.2, lines 28-30). Example 1 shows the composition/article comprises up 20% of uncomplexed cyclodextrin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an adhesive barrier or dressing for medical use comprising composition comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as disclosed by WO '282, and add up to 20% of uncomplexed cyclodextrin to the hydrocolloid phase, as disclosed by US '628. One would have been motivated to do so because US '628 teaches that such an amount of uncomplexed cyclodextrin minimizes odor caused from body fluid. One would reasonably expected formulating adhesive composition useful for personal

care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising uncomplexed cyclodextrin that effectively provides minimal odor from the body fluids.

8. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,231,369 ('369) in view of US 5,714,45 ('445).

US '369 teaches an adhesive sealing material for use in connection to ostomy devices composed of continuous rubber phase and hydrocolloid dispersed in the continuous phase, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-60). Example O, Table III, shows that the styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition, which read on the instantly claimed amounts because claim 4 recites up to 50% polyisobutylene and claim 5 recites up to 15% of styrene polymer. The hydrocolloid is a mixture of more than one hydrocolloid in an amount ranges from 48-56 % (col.8, lines 52-54; Example O, Table III). The composition further comprises oils, medicaments, or bactericides (col.6, lines 33, 45-47). The composition is supplied by release liner, i.e. substrate (col.9, lines 1-2).

The reference does not teach cyclodextrin among the hydrocolloids and its amount, or the material of the substrate as claimed in claim 15.

The material of the substrate does not impart patentability to the claims, and one having ordinary skill in the art would have determined the substrate material according to the specific intended use.

US '445 teaches absorbent article that minimizes odor caused from body fluid through the incorporation of cyclodextrin in the absorbent articles (abstract).

Cyclodextrin forms from 12-20 wt % of the absorbent layer (examples 1, 6, 7). The article further comprises perfumes complexed with cyclodextrin to be released when the cyclodextrin absorbs the odorous molecules so that the perfumes provide "scent signal" signifies the removal of the bad odor so consumer can feel great self confidence (col.2, lines 18-30; col.3, lines 20-22). The absorbent article has backing sheet that is prevent body fluid from escaping from the article, i.e. water-proof (col.13, lines 40-43).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an adhesive composition useful for ostomy devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as disclosed by US '369, and add cyclodextrin complexed with perfumes to the hydrocolloid phase and also provide water-proof backing to the ostomy device as disclosed by US '445. One would have been motivated to do so because US '445 teaches that cyclodextrin minimizes odor caused from body fluid and when cyclodextrin is complexed with perfumes, the perfumes are released when cyclodextrin absorbs the odorous molecules so that the perfumes provide "scent signal" signifies the removal of the bad odor so consumer can feel great self confidence. Further one would have been motivated to add the water proof backing to the device disclosed by US '369 because it will protect fluid permeability and maintain dryness. One would reasonably expected formulating adhesive composition for ostomy devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising

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cyclodextrin complexed with perfumes with minimal odor from the body stoma and “scent signal” signifying removal of the bad odor providing self confidence to the user, as well as a water-proof backing to the device that protects against escape of fluid from the ostomy device.

9. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,367,732 ('732) in view of US '445.

US '732 teaches a skin barrier comprises an adhesive layer comprising discontinuous hydrocolloid phase dispersed in a continuous phase comprising styrene copolymers and polyisobutylene (abstract; col.5, lines 24-26, 49; col.6, lines 35-36; col.8, lines 31-42, 62-64). The adhesive composition further comprises bacteriostatic or fungicidal agents (col.6, line 59). The hydrocolloid phase comprises at least one hydrocolloid, and forms 10-55% of the composition of the adhesive layer (col.8, lines 53-55; col.9, lines 22-23). The styrene copolymer forms 10-40% of the continuous phase (col.9, line 16). The skin barrier further comprises a non-adhesive, water impervious film secured to the adhesive layer (col.3, lines 54-56).

The reference does not teach cyclodextrin among the hydrocolloids.

US '445 teaches absorbent article that minimizes odor caused from body fluid through the incorporation of cyclodextrin in the absorbent articles (abstract). Cyclodextrin forms from 12-20 wt % of the absorbent layer (examples 1, 6, 7). The article further comprises perfumes complexed with cyclodextrin to be released when the cyclodextrin absorbs the odorous molecules so that the perfumes provide “scent signal”

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signifies the removal of the bad odor so consumer can feel great self confidence (col.2, lines 18-30; col.3, lines 20-22).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition for adhesive barrier comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as disclosed by US '732, and add cyclodextrin complexed with perfumes to the hydrocolloid phase as disclosed by US '445. One would have been motivated to do so because US '445 teaches that cyclodextrin minimizes odor caused from body fluid and when cyclodextrin is complexed with perfumes, the perfumes are released when cyclodextrin absorbs the odorous molecules so that the perfumes provide "scent signal" signifies the removal of the bad odor so consumer can feel great self confidence. One would reasonably expected formulating composition for adhesive barriers comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin complexed with perfumes with minimal odor from the body fluid and "scent signal" signifying removal of the bad odor providing self-confidence to the user.

10. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/14282 ('282) in view of US '445.

WO '282 teaches a pressure sensitive adhesive material comprising continuous phase of rubber comprising styrene copolymer and polyisobutylene; and a discontinuous phase comprising hydrocolloid (abstract). The discontinuous phase forms

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15-70 wt % of the composition (page 11, first paragraph). The styrene copolymer forms 10-30 wt % of the composition, and the polyisobutylene forms 20-60 wt % of the composition (page 15, claims 1-4). Examples 1 and 2, page 13, shows that the composition comprising more than one hydrocolloid. The composition comprises bactericides (page 11, third paragraph). The adhesive composition is coated on non-adhesive waterproof film and used in adhesive barrier or dressing for medical use (page 16, claim 13).

The reference does not teach cyclodextrin among the hydrocolloids.

US '445 teaches absorbent article that minimizes odor caused from body fluid through the incorporation of cyclodextrin in the absorbent articles (abstract). Cyclodextrin forms from 12-20 wt % of the absorbent layer (examples 1, 6, 7). The article further comprises perfumes complexed with cyclodextrin to be released when the cyclodextrin absorbs the odorous molecules so that the perfumes provide "scent signal" signifies the removal of the bad odor so consumer can feel great self confidence (col.2, lines 18-30; col.3, lines 20-22).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an adhesive barrier or dressing for medical use comprising composition comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as disclosed by WO '282, and add cyclodextrin complexed with perfumes to the hydrocolloid phase. One would have been motivated to do so because US '445 teaches that cyclodextrin minimizes odor caused from body fluid and when cyclodextrin is complexed with perfumes, the

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perfumes are released when cyclodextrin absorbs the odorous molecules so that the perfumes provide "scent signal" signifies the removal of the bad odor so consumer can feel great self confidence. One would have reasonably expected formulating adhesive barrier or medical dressing comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin complexed with perfumes with minimal odor from the body fluid or wound exudates and "scent signal" signifying removal of the bad odor providing self-confidence to the user.

Response to Arguments

11. Applicant's arguments filed 03/11/2008 as a "pre-appeal brief request or review" have been fully considered but they are not persuasive.

Applicant traverses the obviousness rejections above by arguing that the Examiner has not presented a prima facie case of obviousness and the statements made by the examiner are merely conclusion, not a detailed explanation; hence, the rejections are improper. The mere fact that cyclodextrin absorbs odor in some context doesn't provided a basis for combining US '628 or US '445 with the primary references. Cyclodextrin is not a typical hydrocolloid and had never previously been proposed for use in hydrocolloid-type adhesives in the thirty five years that such adhesives had been known prior to the priority date of the present application. US'369, US'732, and WO'282 list large numbers of hydrocolloids for possible use, but never mention cyclodextrins. Nor do those references suggest a need for or an advantage to be had by adding an odor-absorbent component to the adhesive itself. In US '628 and US '445, odor-absorbency is imparted to a diaper, panty liner, or similar object by providing cyclodextrin microparticles on the surfaces of the fibrous matrices of the absorbent articles. This would give no reason to suppose that cyclodextrin would exhibit such odor-absorbent properties when forming, in combination with another hydrocolloid, the discontinuous phase of a rubber-based adhesive composition.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

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are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, each of US '369, US'732, and WO'282 are directed to personal care articles that contact the body and expose to body fluid. Applicant admits that US '628 and US '445 concern the problem of odor-absorbency in personal care articles such as diaper, panty liner, or similar object. US '628 and US '445 solved the odor problem by providing cyclodextrin microparticles on the surfaces of the fibrous matrices. Adding the cyclodextrin microcapsulated or not does not impart patentability to the claims and not excluded by the claims. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The primary references US '369, US '732, and WO '282 all teach discontinuous phase of hydrocolloid in a continuous phase of adhesive composition, as instantly claimed. US '628 and US '445 are relied upon for the sole teaching of cyclodextrin used as odor absorbent in personal care products. One having ordinary skill in the art would have been motivated to add cyclodextrin to the hydrocolloid phase

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that comprises mixture of more than one hydrocolloid as disclosed by any of the references, motivated by the teaching of any of US '628 or US '445 that cyclodextrin absorb odor caused from body fluid, with reasonable expectation of having adhesive composition comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin providing minimal odor from the body fluid or wound exudates.

In response to applicant's argument that cyclodextrin was known for long before the priority date of the present application is not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). The discovery of a new action underlying a known process does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See *Verdeegal Brothers, Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987). This is believed to be applicable here because anticipation is the epitome of obviousness. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the

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improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argue that the objective evidence of nonobviousness presented by the applicant rebuts the examiner's conclusion that the claims are obvious. Dr. Lipman has worked continuously with pressure-sensitive adhesives since 1965, and with hydrocolloids for over 25 years. Over the course of his professional career, Dr. Lipman has observed a long-felt need for an improved hydrocolloid-containing PSA, particularly an odor- absorbent PSA. The Examiner erred by ignoring this evidence. Applicant also presented evidence of an unexpected synergy that results when cyclodextrin and a second hydrocolloid are used in combination in a PSA of the sort now claimed. The striking improvement in odor absorption achieved by the invention is demonstrated in the

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application as filed and in Dr. Lipman's declaration. Dr. Lipman discovered that the claimed combination of cyclodextrin with another hydrocolloid in a PSA yields two unexpected advantages. First, when combined with another hydrocolloid, the cyclodextrin component exhibits strong odor-absorbing properties. Second, cyclodextrin unexpectedly enhances the adhesive properties and integrity of the composition. The Examiner asserts that Dr. Lipman does not address the individual claims of the application and that the presented "objective evidence of nonobviousness is not commensurate in scope with the claims because the claims are directed to composition, and not method of its use as odor absorbent.

In response to these arguments, applicant's attention is directed to composition, and all the elements of the composition are disclosed by combination of the references. The composition as claimed and the combined teachings of the references are expected to have the same properties since compounds and their properties are non-separable. Upon further review to the declaration, it is noticed that the declaration under 37 CFR 1.132 filed 09/07/2004 is insufficient to overcome the rejection of claims based upon obvious as set forth in the last Office action because: it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. The declaration shows very specific composition having specific adhesives in certain amounts and also specific ranges of cyclodextrin and specific ratio between cyclodextrin and the other hydrocolloids. Further, the declaration is not directed to uncomplexed cyclodextrin as instantly claimed. Additionally, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims, because the claims are directed to composition, and not method of its use as odor absorbent. Objective evidence relevant to the issue of obviousness may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. The evidence may be included in the specification as filed,

accompany the application on filing, or be provided in a timely manner at some other point during the prosecution. The mere fact that an applicant has presented evidence does not mean that the evidence is dispositive of the issue of obviousness. See *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996) where it is stated that to be entitled to substantial weight, the applicant should establish a nexus between the rebuttal evidence and the claimed invention, i.e., objective evidence of nonobviousness must be attributable to the claimed invention.

Minor Informalities

12. The word "dextran" in 4th line of claim 21 is misspelled as "dextrin".
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Isis A Ghali/
Primary Examiner, Art Unit 1611